

AMENDMENTS TO THE CLAIMS

1. (Withdrawn) A stable lyophilized formulation obtainable by lyophilization of an oil-in-water emulsion comprising a bacterial component, an oil, a surfactant, and a stabilizer, as well as an amino acid or urea, which emulsion is characterized in that:

- (a) the bacterial component is encapsulated in an oil droplet;
- (b) the oil droplets are dispersed with a single peak of particle diameter distribution in the aqueous solution; and
- (c) the particle diameter distribution of the oil droplets and turbidity in the aqueous solution are not largely changed before and after lyophilization.

2. (Withdrawn) The stable lyophilized formulation of claim 1, which is formed into an aqueous solution, of which the turbidity is changed by 50% or less compared to that of an aqueous solution before lyophilization.

3. (Withdrawn) The stable lyophilized formulation of claim 1 or 2, wherein the bacterial component is BCG-CWS, and the oil is squalane.

4. (Cancelled)

5. (Withdrawn) The stable lyophilized formulation of claim 3, wherein the amino acid is glycine.

6. (Withdrawn) A process for preparation of a stable lyophilized formulation, which comprises lyophilizing an oil-in water emulsion comprising a bacterial component, an oil, a surfactant, and a stabilizer as well as an amino acid or urea, which emulsion is characterized in that:

- (a) the bacterial component is encapsulated in an oil droplet;

(b) the oil droplets are dispersed with a single peak of particle diameter distribution in the aqueous solution; and

(c) the particle diameter distribution of the oil droplets and turbidity in the aqueous solution are not largely changed before and after lyophilization.

7. (Withdrawn) The process for preparation of a stable lyophilized formulation of claim 6, which formulation is formed into an aqueous solution, of which the turbidity is changed by 50% or less compared to that of an aqueous solution before lyophilization.

8. (Withdrawn) The process for preparation of a stable lyophilized formulation of claim 6 or 7, wherein the bacterial component is a BCG-CWS, and the oil is squalane.

9. (Cancelled)

10. (Withdrawn) The process for preparation of a stable lyophilized formulation of claim 6, wherein the amino acid is glycine.

11. (Withdrawn) A process for preparation of an oil-in-water emulsion wherein the emulsion is negative for agglutination reaction with lectin, and a bacterial component that is selected from a BCG-CWS and *Nocardia rubra*-CWS is encapsulated in oil, which comprises the following steps:

(a) stirring a mixture of a bacterial component that is selected from a BCG-CWS and *Nocardia rubra*-CWS, an oil, and a dispersion-aiding solvent to disperse the bacterial component in the mixture;

(b) evaporating off the dispersion-aiding solvent to form an oil wherein the bacterial component is homogeneously dispersed, or an oil droplet wherein the bacterial component is encapsulated in the oil; and then,

(c) adding an aqueous solution containing a surfactant thereof, and emulsifying the mixture.

12. (Cancelled)

13. (Withdrawn) The process for preparation of an oil-in-water emulsion of claim 11, wherein the bacterial component is a BCG-CWS, and the oil is squalane.

14. (Withdrawn) The process for preparation of an oil-in-water emulsion of claim 11 or 13, wherein the dispersion-aiding solvent is ethanol or toluene.

15. (Withdrawn) The process for preparation of an oil-in-water emulsion of claim 11, wherein the oil droplet is dispersed in a manner that the diameter of the particle is about 100 μm or less.

16. (Withdrawn) A process for preparation of an oil-in-water emulsion, which comprises the following steps:

(a) stirring a mixture of a bacterial component, an oil, and a dispersion-aiding solvent to disperse the bacterial component in the mixture;

(b) evaporating off the dispersion-aiding solvent; and then;

(c) performing the following two-step emulsification process which comprises adding an aqueous solution containing a surfactant:

i) adding an aqueous solution containing a surfactant at a low concentration to the evaporated material, and stirring gently the mixture, thereby performing rough emulsification; and

ii) optionally, adjusting the concentration of the surfactant in the roughly emulsified solution, and stirring vigorously the mixture, thereby performing adequate emulsification in order to provide a desired particle diameter distribution.

17. (Withdrawn) The process for preparation of an oil-in-water emulsion of claim 16, wherein an amount of the surfactant in the aqueous solution containing the surfactant at a low

concentration used in rough emulsification of the two-step emulsification process is 10% or less of the oil.

18. (Withdrawn) The process for preparation of an oil-in-water emulsion of claim 16 or 17, wherein the surfactant is Polysorbate 80 (Tween80).

19. (Withdrawn-previously amended) The process for preparation of an oil-in-water emulsion of claim 16 or 17, wherein the bacterial component is a BCG-CWS or a CWS of *Nocardia rubra*.

20. (Withdrawn) The process for preparation of an oil-in-water emulsion of claim 16, wherein the bacterial component is a BCG-CWS, and the oil is squalane.

21. (Previously Amended) An oil-in-water emulsion wherein the emulsion is dispersed without crude particles, negative for agglutination reaction with lectin, and a Bacillus Calmette-Guerin cell wall skeleton is encapsulated in an oil, and the particle diameter of an oil droplet is 100 μm or less, which emulsion is obtained by the following steps:

(a) stirring a mixture of a Bacillus Calmette-Guerin cell wall skeleton, an oil, and an organic solvent to disperse the Bacillus Calmette-Guerin cell wall skeleton in the mixture;

(b) evaporating off the organic solvent to form an oil wherein the Bacillus Calmette-Guerin cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the Bacillus Calmette-Guerin cell wall skeleton is encapsulated in the oil; and then,

(c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture.

22. (Previously Presented) The oil-in-water emulsion of claim 21, wherein the organic solvent is ethanol or toluene.

23. (Previously Presented) The oil-in-water emulsion of claim 21 or 22, wherein the oil is squalane.

24. (Previously Presented) An oil or an oil droplet wherein a *Bacillus Calmette-Guerin* cell wall skeleton having a particle diameter of about 100 μm or less is homogeneously dispersed.

25. (Previously Presented) The oil droplet of claim 24, wherein the particle diameter is about 25 μm .

26. (Previously Presented) The oil-in-water emulsion of claim 21, wherein the organic solvent is selected from the group consisting of an aromatic hydrocarbon, an aliphatic hydrocarbon, a halogenated hydrocarbon, a lower alcohol, an acetate, an ether and a ketone.

27. (New) An oil-in-water emulsion wherein the emulsion is dispersed without any particles that are visible and have a diameter of 100 μm or more, negative for agglutination reaction with lectin, and a *Bacillus Calmette-Guerin* cell wall skeleton is encapsulated in an oil, and the particle diameter of an oil droplet is 100 μm or less, which emulsion is obtained by the following steps:

(a) stirring a mixture of a *Bacillus Calmette-Guerin* cell wall skeleton, an oil, and an organic solvent to disperse the *Bacillus Calmette-Guerin* cell wall skeleton in the mixture;

(b) evaporating off the organic solvent to form an oil wherein the *Bacillus Calmette-Guerin* cell wall skeleton is homogeneously dispersed, or an oil droplet wherein the *Bacillus Calmette-Guerin* cell wall skeleton is encapsulated in the oil; and then,

(c) adding an aqueous solution containing a surfactant thereto, and emulsifying the mixture.

28. (New) The oil-in-water emulsion of claim 27, wherein the organic solvent is ethanol or toluene.

29. (New) The oil-in-water emulsion of claim 27 or 28, wherein the oil is squalane.